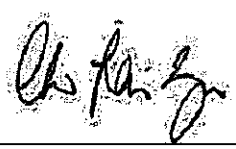
Section 7 510(k) Summary

Re: K_____

CHECK ONLY ONE

☒ 510(k) Summary. Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ 510(k) Statement. I certify that, in my capacity as (*the position held in company by person required to submit the premarket notification, preferably the official correspondent)* of *(company name)*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



Patrick Chow, General Manager
(00852)-2851-6789

05th March, 2014

510(k) Summary

1. Submitter Identification

510(k) Submitter	GRANDWAY TECHNOLOGY (SHENZHEN) LIMITED
Address	Block 6 and 7, Zhu Keng Industrial Zone, Ping Shan, Long Gang District, Shenzhen, Guang Dong, People's Republic of China
Phone Number	(00852)-2851-6789
Fax Number	(00852)-2851-6278
Contact Person	Mr. Patrick Chow
Date of Submission	05th March, 2014

2. Device Identification

Trade Name	Digital Automatic Blood Pressure Monitor BPM20 Series [Model No.: MD20xy] x --- The first character (0, 1, 2 , 3, 4, 5, 6, 7, 8 & 9) is for the minor change revision of device. The mentioned "minor change" refers to those device changes not to be affecting the conformity test results of EMC & safety as well as device performance, i.e. IEC 60601-1, EN 60601-1-2, ETSI EN 301 489-1 V1.92 and ETSI EN 300 328 V1.7.1. y --- The second character (0 & 1) is for the identification of presence of DC jack. Surely, the presence of DC jack does not affecting the conformity test results of EMC & safety as well as device performance, i.e. IEC 60601-1, EN 60601-1-2, ETSI EN 301 489-1 V1.92 and ETSI EN 300 328 V1.7.1.
Common Name	Non-invasive Blood Pressure Measurement System
Classification Name	Non-invasive Blood Pressure Measurement System (CFR 870.1130, Class II, Product Code DXN)

3. Predicate Device

Predicate Device	AViTA Bluetooth Blood Pressure Monitor (Model: BPM656ZB)
Manufacturer	AViTA Coporation
510(k) Number	K072137

4. Device Description

Digital Automatic Blood Pressure Monitor BPM20 Series is a non-invasive blood pressure measurement system for use by medical professional or at home. It is designed to measure the systolic and diastolic blood pressure, and pulse rate of an individual in each measurement and then display the readings on a digital panel.

The device utilizes the oscillometric methodology, in which an inflatable cuff is wrapped around the upper arm of an individual, for blood pressure measurement. This means the monitor detects your blood's movement through your brachial artery and converts the movement into a digital reading.

Certain models of Digital Automatic Blood Pressure Monitor BPM20 Series equipment with Bluetooth transmission function, which enable user to transfer the measurement record from the device to a mobile platform through Bluetooth. User can manage the measurement record by using the mobile application.

The table below illustrate the feature presence in Digital Automatic Blood Pressure Monitor BPM20 Series.

Model	Blood Pressure Measurement	Pulse Rate Measurement	WHO	IHB	LCD Type	Backlight	DC Jack	BLE	Memory
MD2000	✔	✔	LED	✔	Positive Reflective	✗	✔	✗	4 × 120
MD2010	✔	✔	LED	✔	Positive Transmissive	Blue	✔	✗	4 × 240
MD2020	✔	✔	LED	✔	Positive Transmissive	White	✔	4.0	4 × 240
MD2030	✔	✔	✔	✔	Positive Transmissive	Blue	✔	4.0	4 × 240
MD2040	✔	✔	✔	✔	Positive Reflective	✗	✔	✗	4 × 240
MD2050	✔	✔	✔	✔	Positive Transmissive	Blue	✔	✗	4 × 240
MD2060	✔	✔	✔	✔	Positive Transmissive	White	✔	4.0	4 × 240
MD2070	✔	✔	LED	✔	Positive Transmissive	Blue	✔	4.0	4 × 240
MD2080	✔	✔	LED	✔	Negative Transmissive	White	✔	4.0	4 × 240
MD2090	✔	✔	LED	✔	Negative Transmissive	White	✔	✗	4 × 240
MD2001	✔	✔	LED	✔	Positive Reflective	✗	✗	✗	4 × 120
MD2011	✔	✔	LED	✔	Positive Transmissive	Blue	✗	✗	4 × 240
MD2021	✔	✔	LED	✔	Positive Transmissive	White	✗	4.0	4 × 240
MD2031	✔	✔	✔	✔	Positive Transmissive	Blue	✗	4.0	4 × 240
MD2041	✔	✔	✔	✔	Positive Reflective	✗	✗	✗	4 × 120
MD2051	✔	✔	✔	✔	Positive Transmissive	Blue	✗	✗	4 × 240
MD2061	✔	✔	✔	✔	Positive Transmissive	White	✗	4.0	4 × 240
MD2071	✔	✔	LED	✔	Positive Transmissive	Blue	✗	4.0	4 × 240

5. Indication for Use

Digital Automatic Blood Pressure Monitor BPM20 Series is for use by medical professional or home user. The BPM20 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. The inflatable cuff circumference is limited to 17cm – 44cm via 3 different size of cuffs. The 3 different cuff sizes are 17 – 22cm, 22 – 32cm and 32 – 44cm. For Bluetooth capable models, the measurement result can be transmitted to pre-approved mobile devices.

6. Comparison of Technological Characteristics between New Device and Predicate Devices

Digital Automatic Blood Pressure Monitor BPM20 Series is compared to the predicate device, BPM656ZB (K072137) in the device comparison table below.

Comparison between Digital Automatic Blood Pressure Monitor BPM20 Series and predicate device			
Item	**Predicate Device (K072137)**	**Digital Automatic Blood Pressure Monitor BPM20 Series**	**Comment**
Indication for Use	The device is arm type Blood Pressure Monitor that applies oscillometric method to measure human Systolic, Diastolic blood pressure and heart rate. The measurement results are displayed on the LCD and transmitted to Bluetooth enabled devices, such as a PC, a PDA or a printer. The device is designed for adult.	Digital Automatic Blood Pressure Monitor BPM20 Series is for use by medical professional or home user. The BPM20 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. The inflatable cuff circumference is limited to 17cm – 44cm via 3 different size of cuffs. The 3 different cuff sizes are 17 – 22cm, 22 – 32cm and 32 – 44cm. For Bluetooth capable models, the measurement result can be transmitted to pre-approved mobile devices.	Similar
Measurement Method	Non-invasive, Oscillometric	Non-invasive, Oscillometric	Identical
Patient Population	Adult	Age 16 or above	Equivalent
Blood Pressure Measurement Range	Cuff Pressure: 30 - 280 mmHg	Cuff Pressure: 0 - 300 mmHg Systolic Pressure: 50 – 250 mmHg Diastolic Pressure: 30 – 200 mmHg	Similar
Number of User	2 independent users	4 independent users	Similar, improved specification
Memory Space	2 users × 60 memory space	4 users × 120 memory space; or 4 users × 240 memory space (Depends on models identification)	Similar, improved specification

Comparison between Digital Automatic Blood Pressure Monitor BPM20 Series and predicate device			
Item	**Predicate Device (K072137)**	**Digital Automatic Blood Pressure Monitor BPM20 Series**	**Comment**
Resolution of Measurement	1 mmHg	1 mmHg	Identical
Blood Pressure Measurement Accuracy	± 3 mmHg	± 3 mmHg or 2% of reading	Equivalent
Pulse Rate Measurement Range	40 - 199 beats/min	30 - 180 beats/min	Similar
Pulse Rate Measurement Accuracy	± 4 % of the reading	± 5 % of the reading	Similar
Operation Temperature	+5 to +40 °C	+5 to +40 °C	Identical
Operation Humidity	15 – 93% R.H. max	15 – 93% R.H. max	Identical
Storage Temperature	-25 to 70 °C	-25 to 70 °C	Identical
Storage Humidity	Up to 95% R.H. max	Up to 95% R.H. max	Identical
Operation, Storage and Transportation Atmospheric Pressure	700hPa – 1060hPa	700hPa – 1060hPa	Identical
Display Type	LCD	LCD	Identical
Power Source	4 × 1.5 V AA-batteries; and/or AC adaptor (6V/600mA)	4 × 1.5 V AA-batteries; and/or AC adaptor (6V/600mA)	Equivalent
Pressurization Mode	Automatic Inflation	Automatic Inflation	Identical
Deflation Mode	Automatic Exhaust/ Deflation	Automatic Exhaust/ Deflation	Identical
Bluetooth function	Bluetooth 4.0 (2402Hz – 2480Hz)	Bluetooth 4.0 (2402Hz – 2480Hz)	Identical
Cuff Size	23-33cm	17-22cm, 22-32cm, 32-44cm	Similar
Applicable Standard	✧ EN 1060-1 ✧ EN 1060-3 ✧ ANSI/ AAMI SP-10 ✧ IEC 60601-1 ✧ IEC 60601-1-2	✧ EN 1060-1:1995+A2:2009 ✧ EN 1060-3:1997+A2:2009 ✧ IEC 60601-1:2012 ✧ EN 60601-1-2:2007 ✧ FCC Part 15 Subpart B ✧ FCC Part 15 Subpart C ✧ ISO 10993-5:2009 ✧ ISO 10993-10:2010 ✧ IEC 62304:2006 ✧ IEC 81060-2:2009 ✧ ETSI EN 301 489-1 V1.9.2 (2011-09) & ETSI EN 301 489-17 V2.2.1 (2012-09) ✧ ETSI EN 300 328 V1.7.1 (2006-10) & EN 62479:2010 ✧ FDA Radio-Frequency Wireless Technology in Medical Device, Wireless coexistence	Equivalent

Digital Automatic Blood Pressure Monitor BPM20 Series is a non-invasive measuring device and utilizes the oscillometric methodology to measure the blood pressure reading. The key

components of device are: a pressure sensor, a electric valve, an electronic control module, an electric pump and a Bluetooth module. The electric pump inflate (and deflate) the inflatable cuff automatically according to our designed architecture. The Bluetooth module responses to the Bluetooth Version 4.0 (BLE) connection. The predicate device adopts exactly same methodology and key components for measuring blood pressure.

7. Clinical and Non-clinical Tests

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2:2009 as documented in Clinical Test report.

One hundred patients (52 males and 48 females) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left upper arm. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ISO 81060-2:2009.

Non-Clinical Test Summary

Digital Automatic Blood Pressure Monitor BPM20 Series has performed several non-clinical tests to show that all requirement specifications and standard requirements are met. The tests includes the follows:

- EN 1060-1:1995+A2:2009
- EN 1060-3:1997+A2:2009
- IEC 60601-1:2012
- EN 60601-1-2:2007
- FCC Part 15 Subpart B
- FCC Part 15 Subpart C
- ISO 10993-5:2009
- ISO 10993-10:2010
- IEC 62304:2006
- ETSI EN 301 489-1 V1.9.2 (2011-09) & ETSI EN 301 489-17 V2.2.1 (2012-09)
- ETSI EN 300 328 V1.7.1 (2006-10) & EN 62479:2010
- FDA Radio-Frequency Wireless Technology in Medical Device, Wireless coexistence

As all of the clinical and non-clinical testing performed on Digital Automatic Blood Pressure

Monitor BPM20 Series are same as the predicate device. Therefore, no bench test is conducted to show the performance of Digital Automatic Blood Pressure Monitor BPM20 Series is equivalent to the predicate device.

8. Conclusion

Digital Automatic Blood Pressure Monitor BPM20 Series has the similar intended use and same technological characteristics as the predicate device, BPM656ZB (K072137). Moreover clinical testing has demonstrated that no differences in the technological characteristics and questioning on safety or effectiveness to be raised. Thus, Digital Automatic Blood Pressure Monitor BPM20 Series is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 18, 2014

Grandway Technology (Shenzhen) Limited
Patrick Chow
General Manager
Zhu Keng Industrial Zone
Ping Shan, Long Gang District
Shenshen, Guang Dong, 518118 CH

Re: K140583
Trade/Device Name: Digital Automatic Blood Pressure Monitor BPM20 Series
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 9, 2014
Received: May 12, 2014

Dear Patrick Chow,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

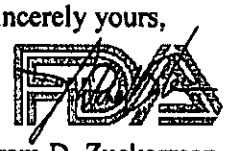
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



forBram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140583

Device Name
Digital Automatic Blood Pressure Monitor BPM20 Series

Indications for Use *(Describe)*
Digital Automatic Blood Pressure Monitor BPM20 Series is for use by medical professional or home user. The BPM20 Series is intended to measure the systolic and diastolic blood pressure, and pulse rate of an adult individual by using a non-invasive technique, in which an inflatable cuff is wrapped around the upper arm of an individual. The inflatable cuff circumference is limited to 17cm – 44cm via 3 different size of cuffs. The 3 different cuff sizes are 17 – 22cm, 22 – 32cm and 32 – 44cm. For Bluetooth capable models, the measurement result can be transmitted to pre-approved mobile devices.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Date: 2014.06.18 08:17:21 -04'00'

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